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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,553	02/24/2005	M.V. Ramana Reddy	06056-0317US1	6059

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EXAMINER

KUMAR, SHAILENDRA

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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01/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,553	Applicant(s) REDDY ET AL.	
	Examiner SHAIENDRA -. KUMAR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 8, 11, 15, 16, 18, 19, 21, 23, 26-34, 37, 42, 53 and 83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 22, 35, 43, 45-47, 50, 52, 54, 56, 60, 62, 68, 70, 76, 77, 84-90 and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,8,11,15,16,18,19,42,43,45-47,50,52-54,56,60,62-68,70,76,77 and 83-91.

DETAILED ACTION

In view of the crossing of the supplemental amendment filed 1/4/08 and the non final office action mailed 1/9/08, the office action of 1/9/08 is hereby vacated and the following office action is in order.

Claims 1-2, 8, 11, 15-16, 18-19, 21-35, 37, 42-43, 45-47, 50, 52-54, 56, 60, 62, 68, 70, 76-77 and 83-91 are pending in this application.

Claims 8, 11, 15-16, 18-19, 21, 23, 26-34, 37, 42, 53 and 83 are withdrawn from the consideration, as being drawn to the non elected invention. Inasmuch as certain claims do not read on the elected species, those claims are indeed none elected, being non readable in the elected species. Claim 90 is included in the examination, as applicants have pointed out.

With respect to the restriction requirement, the same has been made FINAL, see office action of 4/13/07.

Objection to claims 54, 56, 62, 68 and 76 are hereby withdrawn, subsequent to applicants' amendments.

Claim Rejections - 35 USC § 112

1. Claims 43, 45-47, 50, 52, 54, 56, 60, 62, 68, 70, 76-77 and 84-89 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As pointed out in the office action of 4/13/07 these claims fail to comply with the In re Wands factor.

Applicants' argument were fully considered and were not found convincing. Applicants argue that they the presumption with respect to how to make and use the invention. Examiner disagrees. Applicants have made some compounds, but have failed with respect to as to how to use these compounds. Applicants point out that

researchers have identified the cell cycles as being crucial in diseases involving abnormal cell proliferation, and thus anti cancer drugs are available and each drug is effective versus range of cancers, and gives the example of cis-platin. At the out set, instant claimed compounds are nowhere near cis-platin with respect to the structure. Since, cis-platin is well known drug for various cancer, does not lead to believe, that instant claimed compounds will behave the same way as the cis-platin. Cis-platin is well-established drug, which have been rigorously tested in the clinical studies and applicants' comparison of its compounds to cis-platin is without any merit.

Applicants also admit on page 8 of their response that treatment of cancer is unpredictable. Applicants also point out that broadly useful anticancer drugs are available for treatments. The examiner does not dispute the statement, but none of the treatments include structurally similar compounds as claimed in herein.

Applicants have also pointed out to various references to show that in-vitro screening methods are available and later on they end up in in-vivo studies. Again, none of these references suggest compounds, which are structurally similar to those, claimed in herein. Applicants argue that ample guidance and working examples are provided in herein. Just citing NCI data does not give weightage to applicants' data, absent evidence to the contrary. Applicants' assumption that in-vitro data is indicative of in-vivo test is not always true. If it were true, cancer will not exist today.

Applicants in Table 5(page 100-101) present data for some compounds, out of million compounds that can be made out of generic claim in herein. What kind of statistical analysis can be drawn out of the test? Some of the compounds were not even tested. Applicants argue that they have not admitted that activity is not consistent across different diseases. Applicants should see page 60, last but 5th line(last paragraph).

Applicants point out that they agree that there is no "absolute predictability" and concedes that not every compound within the scope of the invention will be useful. Applicants should limit to the scope of the compounds that are effective against some cell lines.

The examiner disagrees with the undue experimentation part of the arguments. In view of the large myriads of the compounds claimed for treating every type of cancers, is indeed part of undue experimentation.

Applicants submit that they don't agree with examiner's position in terms of limiting the scope of the claims to the compounds that they have tested, as examiner has not presented any evidentiary supported reasons for that matter. Applicants should see Carter et al reference, wherein, it clearly shows that for the forty known anticancer agents, none are effective against all the types of cancers.

2. Claims 1-2, 22, 35 and 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamori et al(JP 2001-139550).

Applicants argue that there should be some suggestion and reasonable expectation that the reference renders instant claims prima facie obvious. The suggestion and reasonable expectation comes from the fact the reference teaches structurally similar compounds and composition. Applicants point out that the abstract of the reference demonstrates enormous diversity of the compounds. The examiner believes, that instant claimed compounds are as broad and diversified as the reference compounds. The examiner has very clearly stated as to why the instant claimed compounds would be obvious over prior art of record. Applicants arguments with respect to the use of the compound is of little if any probative value inasmuch as compounds and composition per se are prima facie obvious. Applicants point out to some essential features of the reference. The examiner would like to point out that the reference should be read in its entirety as to what it teaches. Applicants point out to examiner's comment on equivalence of OH and methoxy. Inasmuch the reference have made compounds having OH and OMe substituents, they are indeed equivalent. Applicants question that the examiner has not pointed out to any compound in claim 22, which is taught by the reference. The examiner would like to point that there is no 35 USC 102 issue here. Inasmuch as the substituents are similar, compounds are structurally similar, one of ordinary skill in the art would be motivated to make those compounds.

Applicants' question as to if only English abstract is considered or whole document is considered. It is obvious that the examiner has considered whole document, when he has pointed to certain compounds in the document. The examiner does not have to point out to single species. The generic comparison is enough to render prima facie obvious. There are various compounds described in the reference, and no translation is necessary at this point.

3. Claims 24-25 are again rejected under 35 U.S.C. 103(a) as being unpatentable over US'521, for the reasons of record as set forth in the office action of 4/13/07.

Instant claims are directed to process of making compounds, which are similar to those claimed in herein, see Fig 15, Fig 16 and Fig 25.

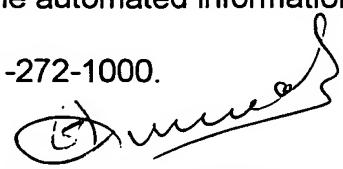
Applicants argue that the examiner is making same error, which was made by an examiner in re Ochiai. The examiner disagrees. In re Ochiai suggests that if compounds are patentable, process of making the compounds is patentable. In the present case, instant compounds have not been found patentable yet.

Applicants argue that they are claiming a method of making an amide, and that is what the reference is teaching. In re Durden, Jr. et al, 226 USPQ 359.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
1/24/08